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OFFICE OF THE DIRECTOR
GROUP 180

Robert Benson
Patent Branch
Office of the General Counsel, DHHS
Building 31, Room 2B62
National Institutes of Health
Bethesda, MD 20892

December 13, 1991

In re Application of
Keith
Serial No. 07/542,149
Filed: June 22, 1990
For: Pertussis Toxin Gene:
Cloning and Expression

DECISION
ON
PETITION

This is a decision on the petition, filed July 18, 1991, under 37 CFR 1.144 requesting review and withdrawal of the restriction requirement.

The petition is DENIED.

The petition indicates primarily that the DNA is not patentably distinct from the protein it encodes because of the informational relationship between DNA and protein.

This argument is not found persuasive. The two kinds of chemical products in question, which are clearly chemical compounds, are patentably distinct on the record of this application even though they are related in the context that the claimed DNA codes for the claimed polypeptides. As set forth by the Examiner, the claimed DNA is not necessary to the preparation of the claimed polypeptides. In addition to the methods noted by the Examiner, the claimed polypeptides may also be made by chemically modifying an isolated naturally-occurring product. Petitioner should note in this regard that claims 2-4 fairly encompass more polypeptides than the polypeptides which may be encoded by the claimed DNA. The claimed DNA may also be used as a molecular weight marker in an electrophoretic separation process. Finally, the burden to the Office of searching these two patentably distinct inventions together is seen from the fact that the classified and literature search required for the claimed polypeptides is different from that required for the claimed DNA.

Furthermore, the Examiner's approach to the issue of restriction between these two chemical compound products is appropriate. As noted by Petitioner, there is no clear form paragraph or MPEP section which clearly addresses restriction between products which are situated in a relationship such as that between the chemical compounds claimed in this application. Consequently, the Examiner has drawn on the tests for patentable distinctness set forth for related products (Markush-type claims, intermediate-final product) and other inventions in other contexts (product and method of making and/or method of using) to demonstrate patentable distinctness from a number of different aspects in the present case.

For these reasons, the restriction requirement is deemed correct.

Petitioner is reminded that the shortened statutory period for responding to the outstanding Office action expired on September 19, 1991.

Charles F. Warren
Deputy Director, Group 180